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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,933	03/27/2007	Galit Levin	85189-13500	2953

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PATENT DEPARTMENT
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WASHINGTON, DC 20006

EXAMINER	
DOUKAS, MARIA E	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
03/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/561,933	LEVIN ET AL.	
	Examiner	Art Unit	
	MARIA E. DOUKAS	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 August 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/4/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/4/2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 4-7, 9, 12-17, 19, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Radiofrequency-driven skin microchanneling as a new way for electrically assisted transdermal delivery of hydrophilic drugs" to Sintov (Sintov) in view of U.S. Patent No. 6,302,874 to Zhang (Zhang).

In Reference to Claims 1, 4-7, 9, 12-17, 19, and 22-24

Sintov teaches a system and method for transdermal delivery of hydrophilic drugs comprising: generating a plurality of microchannels in the skin of the subject

(abstract) using an apparatus (Figure 2) comprising: an electrode cartridge comprising a plurality of electrodes to be oriented generally perpendicular to the skin (Figure 2, micro-electrode array); and a main unit (Figure 2, main unit) comprising a control unit (p. 313, col. 1, "Instruments and Methods") which is adapted to apply radiofrequency energy between two or more electrodes, generating current flow to enable ablation of the stratum corneum to produce microchannels that have a diameter of 10-100 microns and a depth of 20-300 microns (p. 313, "Instruments and Methods"; see MPEP §2144.05 for overlap of ranges), wherein the electrode cartridge is configured for removable attachment to the main unit and can be detached and discarded after use (Figure 2, p. 313, col. 1, "Instruments and Methods"). Sintov further teaches topically applying a water-soluble composition via a patch (p. 314, col. 1) to the skin in which the microchannels are present (p. 315, col. 1) and teaches that this procedure of forming micro-channels can be used in order to transdermally deliver poorly penetrating molecules (abstract). Sintov fails to teach wherein the composition that is applied is a cosmetic composition comprising a drug and a carrier that is further devoid of permeation enhancers and is used to treat a skin condition. Zhang teaches producing transient pores in the skin to facilitate the transdermal delivery of a cosmetic agent composition (col. 7, lines 6-13) comprising at least one cosmetic agent (col. 7, lines 45-48), an acceptable carrier (col. 6, lines 42-53) that is devoid of permeation enhancers (col. 8, lines 33-54, whereby the permeation enhancer is described as being optional), one of the claimed components in claim 9 (col. 1, line 40), and is in one of the claimed forms of claims 12 and 13 (col. 6, lines 53-57) and further teaches wherein the

composition is contained within a patch reservoir that can be attached to the skin (col. 14, lines 20-23). Zhang teaches this patch reservoir composition in order to provide a means to improve the appearance of the skin (col. 1, lines 13-17) as well as treat a variety of skin conditions (col. 5, lines 46-47).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device and method of Sintov to apply the patch containing the cosmetic agent and carrier as taught by Zhang to the skin after micro-channel formation in order to provide a means to improve the appearance of the skin (col. 1, lines 13-17) as well as treat a variety of skin conditions (col. 5, lines 46-47).

4. Claims 8, 10, 11, 18, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Radiofrequency-driven skin microchanneling as a new way for electrically assisted transdermal delivery of hydrophilic drugs" to Sintov (Sintov) in view of U.S. Patent No. 6,302,874 to Zhang (Zhang) as applied to claims 1, 5, 14, and 15 above, and further in view of U.S. Patent No. 6,477,410 to Henley (Henley'410).

In Reference to Claims 8 and 18

Sintov in view of Zhang teaches the device and method of claims 5 and 15 (see above) but fails to teach wherein the cosmetic agent is hydroquinone. Henley'410 teaches delivery of cosmetic agents to the skin that can include hydroquinone in order to remove pigmentation from hyperpigmented areas of the skin (col. 4, lines 65-66). It would have been obvious to one having ordinary skill in the art at the time the invention

was made to have modified the device and method of Sintov in view of Zhang to deliver hydroquinone as taught by Henley'410 in order to remove pigmentation from hyperpigmented areas of the skin (col. 4, lines 65-66). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416).

In Reference to Claims 10, 11, 20, and 21

Sintov in view of Zhang teaches the device and method of claims 1 and 14 (see above) but fails to teach wherein the composition further comprises an antibacterial agent. Henley'410 teaches delivery of antibacterial agents to the skin in order to inhibit bacterial growth (col. 2, lines 9-11; col. 4, lines 49-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device and method of Sintov in view of Zhang to include an antibacterial agent in the composition as taught by Henley'410 in order to inhibit bacterial growth (col. 2, lines 9-11; col. 4, lines 49-50). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416).

5. Claims 1, 5-7, 9, 12-17, 19, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-based vaccines" to

Bramson (Bramson) in view of U.S. Patent No. 2002/0161324 to Henley (Henley'324) in view of U.S. Patent No. 6,302,874 to Zhang (Zhang).

In Reference to Claims 1, 5-7, 9, 12-17, 19, and 22-24

Bramson teaches a system and method for intradermal delivery of an agent comprising: generating a plurality of micro-channels in the skin (Figure 1) by an apparatus comprising: an electrode cartridge (microporation tip comprising ceramic substrate, p. 259, col. 1) comprising a plurality of electrodes (80 micron tungsten wires strapped on the substrate are the electrodes, p. 259, col. 1) to be oriented generally perpendicular to the skin (even though the tungsten wires are strapped around a ceramic substrate, they still have a perpendicular component to them due to the 80 micron diameter they possess. When the substrate with the tungsten wires is placed in the vicinity of the skin, the 80 micron diameter of the wire protrudes perpendicularly from the substrate towards the skin); and a main unit comprising a control unit (p. 258-259; laptop computer, microprocessor control circuitry, three-axis stepper motor assembly with microporation tip holder) which is adapted to apply electrical energy between the two or more electrodes in the vicinity of the skin, enabling ablation of the stratum corneum (p. 259, col. 1, lines 3-9), thereby generating a plurality of microchannels having a diameter of about 10-100 microns and a depth of 20-300 microns (p. 259, col. 1, lines 3-23, see MPEP §2144.05 for overlap of ranges). Bramson further teaches applying a vaccine via the use of a patch applied to the skin after the channels are created (p. 259, col. 1) and further teaches wherein the electrode

cartridge (tip comprising the substrate with tungsten wires) is attached to the control circuitry via copper traces on each side of the substrate. Bramson fails to teach a cosmetic composition comprising a cosmetic agent and a carrier devoid of permeation enhancers is applied to the skin after the channels are created and fails to explicitly teach wherein the electrode cartridge is removably attached to the main unit so that it may be discarded after use.

Henley'324 teaches an electrokinetic delivery device (Figure 2) that comprises a main unit (portion 20) that houses the power source and the control circuitry and a separate distal portion (portion 22) that houses the active electrode and a counter electrode (paragraphs [0035-0036, 0039]) and is therefore an electrode cartridge. This electrode cartridge is detachable from the main unit (portion 20) and is connected via electrical contacts 42 in the electrode cartridge mating with electrical sockets 44 in the main unit portion 22 (Figure 2). Henley teaches the electrode cartridge being detachable from the main unit in order to enable the main unit that contains all the electronics and power source to be reusable multiple times while the electrode cartridge can be disposed of or replaced separately after each individual use (paragraph [0009]).

Zhang teaches producing transient pores in the skin to facilitate the transdermal delivery of a cosmetic agent composition (col. 7, lines 6-13) comprising at least one cosmetic agent (col. 7, lines 45-48), an acceptable carrier (col. 6, lines 42-53) that is devoid of permeation enhancers (col. 8, lines 33-54, whereby the permeation enhancer is described as being optional), one of the claimed components in claim 9 (col. 1, line 40), and is in one of the claimed forms of claims 12 and 13 (col. 6, lines 53-57) and

further teaches wherein the composition is contained within a patch reservoir that can be attached to the skin (col. 14, lines 20-23). Zhang teaches this patch reservoir composition in order to provide a means to improve the appearance of the skin (col. 1, lines 13-17) as well as treat a variety of skin conditions (col. 5, lines 46-47).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Bramson to have the copper traces that provide the connection between the electrode cartridge (ceramic substrate with tungsten wires) and the main unit (control circuitry) be detachable connections like electrical contacts mating with electrical sockets as taught by Henley'324 in order to enable the main unit that contains all the electronics and power source to be reusable multiple times while the electrode cartridge can be disposed of or replaced separately after each individual use (paragraph [0009]).

Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device and method of Bramson to apply the patch containing the cosmetic agent and carrier as taught by Zhang to the skin after micro-channel formation in order to provide a means to improve the appearance of the skin (col. 1, lines 13-17) as well as treat a variety of skin conditions (col. 5, lines 46-47).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over "Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-based vaccines" to Bramson (Bramson) in view of U.S. Patent

No. 2002/0161324 to Henley (Henley'324) in view of U.S. Patent No. 6,302,874 to Zhang (Zhang) as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2002/0010414 to Coston (Coston).

In Reference to Claim 4

Bramson in view of Henley'324 and Zhang teaches the device of claim 1 (see above). Bramson further teaches wherein the microporation parameters can be controlled by the user interface, but fails to explicitly teach wherein the electrical energy is of radiofrequency. Coston teaches an apparatus that creates at least one microchannel in the skin by applying electrical energy between two or more electrodes (paragraphs [0013-0015]) and teaches that the electrical energy used is of radio frequency (paragraph [0016], wherein the frequency of 30-10,000 kHz falls w/in radio frequency range). Although Bramson fails to explicitly teach the frequency parameter that is used, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the parameter to fall within the radiofrequency range as taught by Coston, since it has been held that where the general conditions of a claim are known in the prior art, discovering an optimum or workable range involves only routine skill in the art (MPEP §2144.05).

7. Claims 8, 10, 11, 18, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-based vaccines" to Bramson

(Bramson) in view of U.S. Patent No. 2002/0161324 to Henley (Henley'324) in view of U.S. Patent No. 6,302,874 to Zhang (Zhang) as applied to claim 1, 5, 14, and 15 above, and further in view of U.S. Patent No. 6,477,410 to Henley (Henley'410).

In Reference to Claims 8 and 18

Bramson in view of Henley'324 and Zhang teaches the device and method of claims 5 and 15 (see above) but fails to teach wherein the cosmetic agent is hydroquinone. Henley'410 teaches delivery of cosmetic agents to the skin that can include hydroquinone in order to remove pigmentation from hyperpigmented areas of the skin (col. 4, lines 65-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device and method of Bramson in view of Henley'324 and Zhang to deliver hydroquinone as taught by Henley'410 in order to remove pigmentation from hyperpigmented areas of the skin (col. 4, lines 65-66). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416).

In Reference to Claims 10, 11, 20, and 21

Bramson in view of Henley'324 and Zhang teaches the device and method of claims 1 and 14 (see above) but fails to teach wherein the composition further comprises an antibacterial agent. Henley'410 teaches delivery of antibacterial agents to the skin in order to inhibit bacterial growth (col. 2, lines 9-11; col. 4, lines 49-50). It

would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device and method of Bramson in view of Henley'324 and Zhang to include an antibacterial agent in the composition as taught by Henley'410 in order to inhibit bacterial growth (col. 2, lines 9-11; col. 4, lines 49-50). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416).

Response to Arguments

8. Applicant's arguments with respect to claims 1 and 4-24 have been considered but are not applicable in view of the new ground(s) of rejection based on newly cited and applied art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD
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